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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,578	08/20/2003	Patrick Jay Lutz	05408/100K559-US1	5199
7278	7590	08/20/2008		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER PURDY, KYLE A	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 08/20/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/644,578	<b>Applicant(s)</b> LUTZ ET AL.	
	<b>Examiner</b> Kyle Purdy	<b>Art Unit</b> 1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08/20/2003, 09/27/2007 and 07/03/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7-11, and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The Examiner acknowledges receipt of the amendments filed on 07/30/2008 wherein claims 1, 4, 20 have been amended, claims 24 and 25 have been newly added and claims 3 and 6 have been cancelled.

2. Claims 1, 2, 4, 7-11 and 20-25 are presented for examination on the merits. The following rejections are made.

### ***Response to Applicants' Arguments***

3. Applicants arguments filed 07/30/2008 regarding the rejection of claim 22 made by the Examiner under 35 USC 112, second paragraph have been fully considered and they are found persuasive. This rejection has been overcome by amendment.

4. Applicants arguments filed 07/30/2008 regarding the rejection of claims 1-3, 7, 10 and 23 made by the Examiner under 35 USC 103(a) have been fully considered and they are found persuasive. This rejection has been overcome by amendment.

5. Applicants arguments filed 07/30/2008 regarding the rejection of claim 1-4, 6-11 and 20-22 made by the Examiner under 35 USC 103(a) over Rothenburger et al. (US6121302) in view of Willingham (US 5424324) have been fully considered but they are not found persuasive.

6. Applicants arguments filed 07/30/2008 regarding the rejection of claim 1-4, 6-11 and 20-22 made by the Examiner under 35 USC 103(a) over Farina et al. (US 5405862) in view of Trinh et al. (US 6682694) have been fully considered but they are not found persuasive.

7. In regards to the 103(a) rejections, Applicant asserts the following:

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A) None of the cited references disclose or suggest how a synergistic effect would be achieved by combining the components as presently claimed.

8. With respect to assertion A, Applicants arguments are not found persuasive. It is noted that Applicant has narrowed the concentrations of their component species to specific weight percentages wherein the a) aldehyde donor is present from about 5% to 95%, b) DMH is present up to about 30% and c) DHA is present from about 0.5% o about 95% by weight of the composition. However, the combination of Rothenburger and Trinh would motivate making such a composition with such components (see below) and in doing so would result in a composition having synergistic properties. Albeit, Trinh suggests including dehydroacetic acid at a maximum of 0.2%, it would have been obvious to one of ordinary skill in the art to adjust the concentration of DHA knowing that is has antibacterial/preserving properties to optimize the antimicrobial efficacy of the composition.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**10. Claims 1, 2, 4, 7-11, 20-22, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenburger et al. (US 6121302; of record) in view of Trinh et al. (US 6682694; of record).**

11. Rothenburger et al teach a highly stable formulation having broad-spectrum preservative properties. The formulation is an admixture of dialkanol-substituted dimethylhydantoin, one or more isothiazolone compounds, a hydantoin stabilizer, and a hydroxyl solvent (see abstract; see instant claims 1 and 20). The formulation has a free formaldehyde content of less than 0.2% and is beneficial for preserving various aqueous compositions, including household and industrial products, and especially personal care products, which require a less acidic pH range than in which isothiazolone is stable in the presence of cationic salts (see abstract; see instant claims 8 and 21). Compositions are disclosed, see Example 1 which teaches a composition comprising Glydant® (a mixture of 1,3-dimethylol-5,5-dimethylhydantoin (DMDMH) and monomethyldimethylhydantoin (MDMH)) and a dimethylhydantoin (DMH) stabilizer (see instant claims 1 and 4). The composition is to contain about 20 to 95 wt % of a formaldehyde donor (i.e. Glydant®), 0.02 to 90 wt % of an isothiazolone, 1 to 30 wt % of an alkyl hydantoin stabilizer and up to 60 wt % of a hydroxyl solvent (see claim 3; see instant claims 9, 10, 24 and 25).

12. Rothenburger fails to teach dehydroacetic acid and its sodium salt in the composition.

13. Trinh teaches a preservative composition including imidazolidinedione compounds such as DMDMH for being effective against bacteria. Trinh suggests the inclusion of dihydracetic acid (DHA) and its sodium or potassium salts from about 0.005% to about 0.02% of the composition (see column 11, lines 1-5; see instant claims 1, 2, 11, 20 and 22). Trinh teaches the preservatives can be used in mixtures in order to control a broad range of microorganisms.

14. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Rothenburger and Trinh with a reasonable

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expectation for success in arriving at a composition comprising an aldehyde donor such as DMDMH, a stabilizer such as DMH and a preservative such as DHA. Rothenburger specifically suggests making a composition comprising DMDMH (or a mixture of DMDMH and MDMH), DMH at the recited weight percentages. Rothenburger fails however to include the preservative DHA and its corresponding sodium salt. Trinh cures this deficiency. One would have been motivated to include DHA and its sodium salt because in doing so would add a preserving effects to the final composition. With respect to the recited weight percentage of DHA, it is obvious. One of ordinary skill in the art would have been motivated to adjust the relative concentration of DHA with the goal optimizing its preserving efficacy, thereby increasing the lifetime of the solution. With respect to the weight ratio of the aldehyde donor and DHA being from about 0.05:30 (or 1:600) to 30:0.05 (or 600:1) is obvious. As Rothenburger discloses using the formaldehyde donor from about 20% by weight of the composition and Trinh discloses using DHA at about 0.2% by weight of the compositions, the resultant weight ratio of donor to DHA is 100:1, a value well within the instantly claimed range. Therefore, a composition comprising a formaldehyde donor, DMH and DHA is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

15. Note, for the purposes of searching for and applying art, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'the recitation of 'consisting essentially of' will be construed as equivalent to 'comprising. See MPEP 2111.03.

**16. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farina et al. (US 5405862; of record) in view of Trinh et al. (US 6682694; of record).**

17. Farina teaches a preservative composition comprising 27.4% of MDMH, 26.1% of DMDMH and 4.2% of DMH (see Table 5).

18. Farina fails to teach the composition as comprising DHA.

19. Trinh teaches a preservative composition including imidazolidinedione compounds such DMDMH for it effective against bacteria. Trinh further teaches the use of DHA in an amount of 0.005-0.2% by weight of the composition (see column 11, lines 1-5). Trinh teaches the preservatives can be used in mixtures in order to control a broad range of microorganisms.

20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Farina and Trinh to arrive at a synergistic antibacterial composition free of isothiazolones. Farina is directed to antimicrobial composition comprising DMH, DMDMH and MDMH. Farina fails to include DHA in their composition. Trinh cures this deficiency. Trinh specifically teaches that DHA has broad range antimicrobial activity thereby making a useful preservative component of compositions. One would have been motivated to include DHA in the composition of Farina with a reasonable expectation of success since Trinh teaches mixtures of preservative may be utilized to control a broad range of microorganisms. With respect to the limitation that the composition be free of isothiazolone, the combination of applied references meets such a limitation. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

21. Note, for the purposes of searching for and applying art, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'the recitation of 'consisting essentially of' will be construed as equivalent to 'comprising. See MPEP 2111.03.

### ***Conclusion***

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
August 11, 2008*

*/Sharmila Gollamudi Landau/*

Supervisory Patent Examiner, Art Unit 1611